

COVID-19 Vaccine Information Brief

February 25, 2022

Changes to the document from the previous version are highlighted in yellow.

IMPORTANT/NEW COVID-19 Vaccine Information

- Clinical Guidance Update: COVID-19 vaccination - Updated February 22, 2022
- FAQ Regarding Clinical Guidance Update
- Pfizer Controlant Data "SAGA Logger"
- Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training
- Vaccine Expiration Date Resources
- V-Safe After Vaccination Health Checker - New Poster

Clinical Guidance Update: COVID-19 vaccination - Updated February 22, 2022

CDC updated [COVID-19 vaccination guidance](#) with additional information to help vaccine providers determine the optimal interval between the first and second dose of an mRNA vaccine series, based on the individual patient. These additional considerations followed a thorough evaluation of the latest safety and effectiveness data, and evidence from hundreds of millions of COVID-19 vaccines that have already been safely administered in the United States, and the billions of vaccines administered in other countries.

[New data](#) indicate some people ages 12 through 64 years—and especially males ages 12 through 39 years—would benefit from getting their second mRNA COVID-19 vaccine dose 8 weeks after receiving their first dose. Extending the time interval between primary mRNA COVID-19 vaccine doses from the FDA-approved or authorized 3 weeks (Pfizer-BioNTech) or 4 weeks (Moderna) to 8 weeks may help increase how long protection lasts against COVID-19. It may also help lower the (small) risk of myocarditis (inflammation of the heart muscle) and pericarditis (swelling of tissue around the heart), which has been associated—mostly among adolescent and young adult males—with mRNA COVID-19 vaccination.

It's important to note this update does not apply to everyone.

- Providers should continue to recommend the 3-week or 4-week interval for people who are moderately or severely immunocompromised, adults ages 65 years and older, and others who may need early protection due to concern about an increased risk of severe illness from COVID-19 or high levels of community transmission.
- People ages 12 years and older with moderate or severe immunocompromise should receive three doses in their mRNA primary vaccine series and should receive a booster dose with an mRNA vaccine at least 3 months after completing their third primary series dose.

Regardless of the interval between the first and second dose, mRNA vaccines are highly effective at reducing the risk of hospitalization and serious complications from COVID-19 infection. And people who have already received their primary mRNA series at the 3-week or 4-week interval remain well-protected—especially if they have received a booster dose.

Primary series vaccine manufacturer	Age group	Number of doses in primary series	Number of booster doses	Interval between 1 st and 2 nd dose *	Interval between primary series and booster dose
Pfizer-BioNTech	5–11 years	2	NA	3 weeks	N/A
Pfizer-BioNTech	≥12 years	2	1	3-8 weeks**	≥5 months
Moderna	≥18 years	2	1	4-8 weeks**	≥5 months
Janssen	≥18 years	1	1	NA	≥2 months

*For the vaccination schedule for people who are moderately or severely immunocompromised, see [Table 3](#).

**An 8-week interval may be optimal for people ages 12 years through 64 years, and especially for males ages 12 through 39 years, who are not moderately or severely immunocompromised. A shorter interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second dose remains the recommended interval for: people who are moderately or severely immunocompromised; adults ages 65 years and older; and others who need early protection due to increased concern about community transmission or risk of severe disease.

Updated COVID-19 Vaccine Web Resources

- [Interim Clinical Care Considerations for COVID-19 Vaccination](#)
- [COVID-19 Vaccine Booster Shots](#)
- [COVID-19 Vaccines are Effective](#)
- [COVID-19 Vaccines for People with Allergies](#)

FAQ Regarding Clinical Guidance Update

Q: Can you explain this new guidance that CDC is providing related to dose intervals for mRNA primary series vaccination?

A: CDC is providing healthcare providers with additional information to factor into COVID-19 vaccine recommendations for their patients. Some people ages 12 through 64 years—and especially males ages 12 through 39 years—may benefit from getting their second mRNA COVID-19 vaccine dose 8 weeks after receiving their first dose, instead of after the FDA-approved or FDA-authorized 3 weeks (Pfizer-BioNTech) or 4 weeks (Moderna).

Recent safety and effectiveness [data](#) illustrate that a longer time interval between the first and second mRNA COVID-19 vaccine dose gives the body a chance to build a stronger immune response, increasing the effectiveness of these vaccines, and offering individuals greater protection against COVID-19. A longer interval between primary doses can also help lower the rare risk of myocarditis and pericarditis following vaccination. Although rare, some cases have been reported—mostly among adolescent and young adult males—after receiving the Pfizer-BioNTech or Moderna vaccines.

Q: For whom might an 8-week interval between the 1st and 2nd doses of mRNA COVID-19 vaccines be especially optimal?

A: The 8-week interval is optimal for patients ages 12 through 64 years—and particularly males ages 12 through 39 years—who are not moderately or severely immunocompromised, and for whom there is no

increased concern about community transmission or severe disease. The Advisory Committee on Immunization Practices recommends using a 1-inch needle for children 1 year of age and older when administering vaccines to ensure the vaccine is deposited well into the muscle tissue. A 5/8-inch needle may be used in some circumstances if the skin is stretched tightly, and subcutaneous tissues are not bunched. Healthcare providers should use professional judgment for the situations in which a 5/8-inch needle is required.

Q: Would an interval between the 1st and 2nd doses of mRNA COVID-19 vaccines longer than 8 weeks be even better?

A: Extending the interval beyond this time has not been shown to provide additional benefits.

Q: Are mRNA vaccine doses administered later than the recommended interval valid?

A: mRNA vaccine doses administered at any time after the recommended interval are valid and do not need to be repeated.

Q: For whom might the FDA-approved or FDA-authorized 3- or 4-week intervals between 1st and 2nd doses of mRNA COVID-19 vaccines continue to be optimal?

A: Vaccine providers should continue to recommend the 3- or 4-week interval for patients who are at higher risk of having an inadequate response to the first mRNA vaccine dose (such as people who are moderately or severely immunocompromised), patients who are at higher risk for severe complications of COVID-19 (such as adults ages 65 years and older), and patients who need rapid protection, such as during high levels of community transmission. Providers can help patients determine the best interval between vaccine doses by examining their balance of benefits and risks.

Q: Why are children ages 5-11 years not recommended to consider a longer interval between the 1st and 2nd doses of mRNA COVID-19 vaccines?

A: There are currently no data available for children younger than age 12 years regarding any impact of intervals longer than 3 weeks between the 1st and 2nd doses of the Pfizer-BioNTech COVID-19 vaccine, which is an mRNA vaccine. Children younger than 12 years are not eligible for any other COVID-19 vaccine at this time.

Pfizer Controlant Data “SAGA Logger”

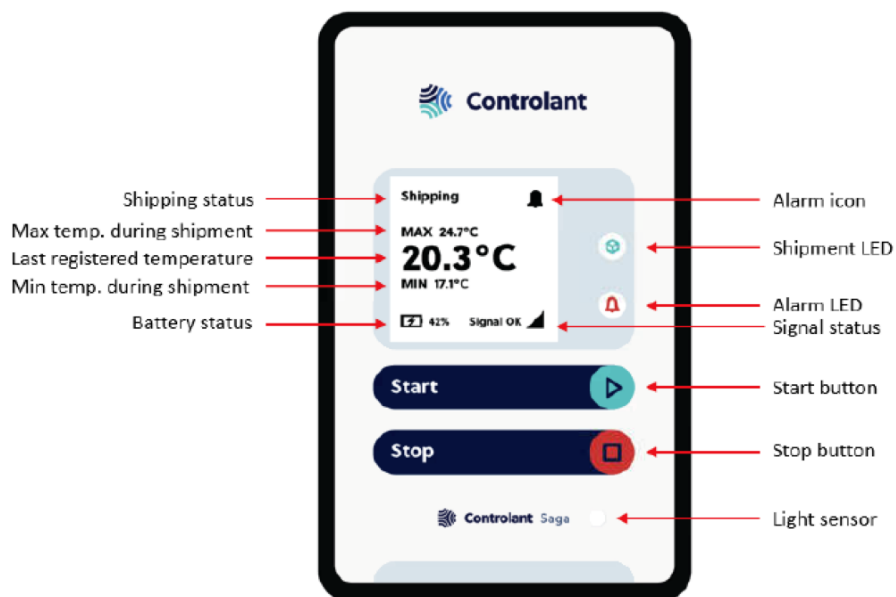
Pfizer vaccine shippers will begin transitioning to an updated data logger from Controlant. This new device called “SAGA Logger” will provide improved performance for monitoring and reporting during shipment. The key improvements to this device include:

- Enhanced location accuracy with WiFi
- Utilization of the 4G cellular network
- Interactive LCD display with an improved user interface
- 150 days of backup storage when no cloud is available
- Longer battery life
- Improved data transmission capability

The new interactive LCD tracker display shows current temperatures and the minimum and maximum temperatures of the shipper contents during transit. The screen also includes an easy-to-read status indicator for the safer NiMH extended-life battery.

The new SAGA Logger is slightly larger in size and, as with the previous logger, requires return shipping in the packaging materials provided with the order. For additional information or questions, visit the Pfizer Webinar Series for Healthcare Providers presented by Pfizer. [Click HERE](#) for a complete schedule of trainings for February and March and to access links and passwords for each course.

Controlant SAGA Logger



Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training

At this time, the Medical Affairs team is continuing to educate providers on Purple, Gray, and Orange caps as well as medical updates.

Session topics include:

- Use of each vaccine presentation, including storage, handling, preparation, and administration for:
- Ages 5 through 11 Years: **DILUTE BEFORE USE/Orange Cap**
- Ages 12 Years and Older:
- **DO NOT DILUTE/Gray Cap**
- **DILUTE BEFORE USE/Purple Cap**
- Recent medical updates regarding the vaccine
- An overview of healthcare provider resources
- Question and answer session

Please click on the links below to join the sessions at the designated times.

Date & Time	Password
Attendee link – Tuesday, March 1 - 3pm ET	svU8YkF58Qc
Attendee link – Wednesday, March 2 - 12pm ET	3jJ2WJMgeb8
Attendee link – Thursday, March 3 - 12pm ET	4UBrwQDva77

Vaccine Expiration Date Resources

Always be sure to check the manufacturer's website to obtain the most up-to-date expiration dates for COVID-19 vaccines. It is important for healthcare providers to update vaccine expiration dates in IRIS. Questions regarding IRIS vaccine inventory and adjusting expiration dates can be directed to the IRIS Helpdesk at 800-374-3958.



For EUA COVID-19 vaccines that do not have a final expiration date, the CDC has set an expiration date of **12/31/2069 to serve as a placeholder date**. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer's website. **It is important for healthcare providers to update vaccine expiration dates in IRIS.**

The Pfizer COVID-19 vaccine:

It is important for all healthcare providers to double check all shelf life extensions for all Pfizer products.

Pfizer does not have an expiration date look up tool for these vaccines. **The date on the label is NOT the expiration date, instead, each vial has the lot number and date of manufacture printed on the label.** Pfizer does provide guidance for expiration dates on their [website](#).

- Regardless of storage condition, **GRAY CAP** and **ORANGE CAP** vaccine vials should not be used after 9 months from the **date of manufacture** printed on the vial and cartons.
- The **PURPLE CAP** vaccine vials with an **expiry date** of September 2021 - February 2022 (printed on the label) may remain in use for 3 months beyond the printed date if vials are maintained in approved storage conditions (-90°C to -60°C, -130°F to -76°F).
- Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 (**ORANGE CAP**) years of age may be stored at refrigerated temperatures between 2°C and 8°C (36°F and 46°F) for up to 10 weeks. **Vaccine initially distributed is nearing or has met the 10-week beyond-use date (BUD).**
 - **Reminders for providers:**
 - Vaccine may be stored in a refrigerator unit between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.
 - Do NOT use vaccines stored in the refrigerator after 10 weeks. Discard appropriately.
 - Use a tracking system to ensure the vaccine is not used after the BUD. CDC has tracking labels to monitor storage times at [Pfizer-BioNTech COVID-19 Vaccine \(5 Through 11 Years of Age\) | CDC](#)

 Expiry information for Ages 5 through 11 DILUTE BEFORE USE Orange Cap presentation and Ages 12 years and older DO NOT DILUTE Gray Cap presentation		 Expiry information for Ages 12 years and older DILUTE BEFORE USE Purple Cap presentation	
Printed Manufacturing Date	9-Month Expiry Date	Printed Expiry Date	Updated Expiry Date
06/2021	28-Feb-2022	September 2021	December 2021
07/2021	31-Mar-2022	October 2021	January 2022
08/2021	30-Apr-2022	November 2021	February 2022
09/2021	31-May-2022	December 2021	March 2022
10/2021	30-Jun-2022	January 2022	April 2022
11/2021	31-Jul-2022	February 2022	May 2022
12/2021	31-Aug-2022		
01/2022	30-Sep-2022		
02/2022	31-Oct-2022		

Janssen COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to www.vaxcheck.inj/

Moderna COVID-19 vaccine:

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Go to www.modernatx.com/covid19vaccine-eua/

CDC's [COVID-19 Vaccine Expiration Date Tracking Tool](#) can help providers keep track of the expiration date by lot number.

J&J/Janssen		Moderna		Pfizer	
Lot Number	Expiration	Lot Number	Expiration	Lot Number	Expiration
1822809	3/7/2022	088D21A	2/25/2022	EY0581	2/28/2022
215C21A	3/8/2022	015G21A	2/25/2022	FD0810	2/28/2022
1822811	3/20/2022	016E21A	3/1/2022	30125BA	2/28/2022
203F21A	3/21/2022	939914	3/2/2022	30135BA	2/28/2022
204F21A	3/22/2022	019G21A	3/2/2022	EY0582	2/28/2022
218C21A	4/9/2022	019E21A	3/2/2022	30130BA	2/28/2022
1855194	4/9/2022	017E21A	3/3/2022	FE3592	2/28/2022
211D21A	4/11/2022	018E21A	3/3/2022	FD7220	2/28/2022
213D21A	4/11/2022	020E21A	3/4/2022	FE3590	2/28/2022
1855191	4/11/2022	046G21A	3/5/2022	30145BA	2/28/2022
220C21A	4/11/2022	939915	3/5/2022	FD7218	2/28/2022
208D21A	4/24/2022	047E21A	3/6/2022	FE3594	2/28/2022
1855835	4/27/2022	939916	3/9/2022	30155BA	3/31/2022
1855190	4/27/2022	939899	3/10/2022	FF2587	3/31/2022
219C21-2A	5/2/2022	058E21A	3/10/2022	FF2593	3/31/2022
202D21A	5/2/2022	939917	3/10/2022	FF2589	3/31/2022
204D21A	5/3/2022	059E21A	3/11/2022	FF2588	3/31/2022
1855836	5/7/2022	939918	3/12/2022	FF8841	3/31/2022
201F21A	5/8/2022	002F21A	3/14/2022	FF2590	3/31/2022
				FF8839	3/31/2022

V-safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: posted on the vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
- [V-safe after vaccination health checker website](#)
- [V-safe Print Resources](#)
- [V-safe Poster-11x17](#)
- [Vaccine Adverse Event Reporting System \(VAERS\)](#)